

REMARKS

Claims 6-8 and 10-13 have been rejected under 35 USC 103(a) as being unpatentable over Muromachi et al. Applicants once again respectfully traverse this ground of rejection and urge reconsideration in light of the following comments.

As explained previously, the instant invention is directed to an oyster extract mixture containing 0.05% to 0.4% zinc by dry weight with the zinc being combined with peptides of the oyster.

Another embodiment of the present invention is directed to an oyster extract containing zinc in an amount of from 6% to 14% by dry weight, with the zinc being combined with peptides of the oyster having a molecular weight of 3,000 to 5,000 daltons, as determined by gel filtration chromatography.

The oyster extract can be obtained by a process which comprises the steps of extracting raw oysters with hot water to obtain an oyster residue, adjusting the pH of the oyster residue to 2-4 and neutralizing the pH-adjusted oyster residue to obtain a precipitate. The oyster extract can also contain manganese in an amount of 0.05-0.2% and magnesium in an amount of 1-2%. Additionally, the oyster extract can be combined with a second oyster extract obtained by hot water extraction.

The present invention is based on the discovery that when zinc is combined with peptides contained in an oyster extract, the zinc has a much higher bioavailability than when administered in other forms. Zinc is an essential nutrient in human nutrition but it has been determined that there is a sub-optimal zinc level in the population. To improve zinc nutrition, it has been recommended that food sources with a high zinc concentration be consumed. However, zinc in foods have varying adsorption rates due to various dietary factors including chemical characteristics. Generally, about 30% of zinc is absorbed after ingestion. The presently claimed invention was arrived at to provide a zinc composition having

an improved bioavailability and a method of providing this zinc composition.

As discussed previously, the Muromachi et al reference discloses a whey mineral containing at least 0.8 g/kg or above of zinc which, in Example 6, can be added to an oyster meat extract, seaweed powder and zinc-containing liquid formula to prepare a liquid formulation containing 8 mg of zinc per every 1,500 ml of formula.

In the Office Action, the Examiner states that the oyster extract mixture of Muromachi et al does have a zinc concentration as currently claimed and, while the oyster extract alone may not have the claimed zinc concentration, the conclusion of unexpected results for the claimed zinc concentration is unsupported by any factual evidence of record.

In order to overcome the showings in the Muromachi et al reference, Applicant is enclosing herewith a Declaration Under 37 CFR 1.132 which shows the improved bioavailability of zinc in the oyster extract of the present invention. Test mice were fed a casein-based low zinc diet, a basal diet with 5 µg/g of zinc as zinc carbonate hydroxide and a basal diet with 5 µg/g of zinc as the zinc-rich powder obtained from an oyster extract of the present invention. After feeding for four weeks, the blood, liver, muscles and tibia were isolated, washed, blotted and weighed. The zinc deposition in the plasma, erythrocytes, liver, muscles and tibia are summarized in Table 2 of the enclosed Declaration.

As shown in Table 2 of the Declaration, the zinc-rich powder of the present invention which is obtained by extracting oysters with hot water, adjusting the oyster residue to a pH of from 2-4, filtering the residue extract and neutralizing the pH of the filtered extract according to the present invention resulted in a much higher zinc bioavailability than would be expected. This clearly establishes the patentability of the presently claimed invention over the prior art cited by the Examiner.

Also enclosed herewith for the Examiner's benefit are articles published by the present inventor which were published after the filing date of the present application and deal with the action and bioavailability of zinc in the body.

In the last Response, it was mistakenly stated that zinc, manganese, etc. were water-soluble. This is clearly a misstatement because, as discussed at specification page 2, it is well known that these minerals are water-insoluble.

Favorable consideration is respectfully solicited.

Respectfully submitted,


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Encl: Declaration Under 37 CFR 1.132
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